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EXAMINER KASZTEJNA, MATTHEW JOHN				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/518,222

Applicant(s)

DIRUSSO ET AL.

Examiner

MATTHEW J. KASZTEJNA

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/19/8, 10/22/8.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-17 and 19-20 in the reply filed on September 18, 2008 is acknowledged.

Claim 18 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 18, 2008.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9-12 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,916,147 to Boury.

In regard to claims 1, 11 and 19-20, Boury discloses an endoscope comprising: a handle 22; and a shaft 30 extending from the handle, the shaft having a front end comprising a first active deflection section 36a including a plurality of rings pivotably connected to each other and a second active 36b deflection section including a plurality of rings 40 pivotably connected to each other, wherein the first active deflection section is limited to deflection in a first plane and the second active deflection section is limited to deflection in a second different plane, and wherein the first plane is angled to the second plane (see Figs 2-3 and Col. 7, Lines 64 - Col. 8, Line 51).

In regard to claim 2, Boury discloses an endoscope wherein the first plane is about 75° to about 90° relative to the second plane (see Fig. 2 and Col. 8, Lines 18-38)).

In regard to claim 3, Boury discloses an endoscope, wherein the second active deflection section is limited to deflect only in left and right directions relative to the handle (see Col. 7, Lines 64 - Col. 8, Line 51).

In regard to claim 4, Boury discloses an endoscope, wherein the first active deflection section is limited to deflect only in upward and downward directions relative to the second active deflection section (see Col. 7, Lines 64 - Col. 8, Line 51).

In regard to claims 5-6 and 12, Boury discloses an endoscope, wherein the first active and/or second deflection sections are *adapted* to deflect through an angle of about 110° to about 220° (see Col. 8, Lines 18-23).

In regard to claim 9, Boury discloses an endoscope, wherein the endoscope comprises a cystoscope comprising means for viewing 360° inside of a generally spherical shape through a fixed entrance into the generally spherical shape by a camera or an optical lens at the front end of the shaft without axially rotating the shaft (see Col. 1, Lines 18-23).

In regard to claim 10, Boury discloses an endoscope, wherein the first active deflection section comprises rings 40 pivotably connected to each other to form a frame of the first active deflection section, wherein a connection of the rings to each other comprises balls located in sockets of the rings and at least one connecting member extending through a hole in the balls (see Fig. 7).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-8 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,916,147 to Boury in view of U.S. Patent No. 6,639,213 to Ogura et al.

In regard to claims 7-8 and 13-14, Boury discloses an endoscope comprising: a handle 22; and a shaft 30 extending from the handle, the shaft having a front end comprising a first active deflection section 36a including a plurality of rings pivotably connected to each other and a second active 36b deflection section including a plurality of rings 40 pivotably connected to each other, wherein the first active deflection section is limited to deflection in a first plane and the second active deflection section is limited to deflection in a second different plane, and wherein the first plane is angled to the second plane (see Figs 2-3 and Col. 7, Lines 64 - Col. 8, Line 51). Boury are silent with respect to a brake actuator located on the handle adapted to lock one of the active deflection sections at a desired position. Ogura et al. teach of an analogous apparatus having a first control subsection 42 that includes, as shown in FIG. 5, angling knobs 42a and 42a' and first locking levers 42b and 42b'. The angling knobs 42a and 42a' are used to bend the first bending portion 24. The first locking levers 42b and 42b' are used

to lock the angling knobs 42a and 42a' at desired angular positions (see Figs. 5 and 20a-c). It would have been obvious to one skilled in the art at the time the invention was made to provide a brake actuator on the handle in the apparatus of Boury to provide an alternate means of locking the catheter in a desired position during use as taught by Ogura et al.

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,916,147 to Boury in view of U.S. Patent No. 5,938,588 to Grabover et al.

In regard to claims 15-17, Boury discloses an endoscope comprising: a handle 22; and a shaft 30 extending from the handle, the shaft having a front end comprising a first active deflection section 36a including a plurality of rings pivotably connected to each other and a second active 36b deflection section including a plurality of rings 40 pivotably connected to each other, wherein the first active deflection section is limited to deflection in a first plane and the second active deflection section is limited to deflection in a second different plane, and wherein the first plane is angled to the second plane (see Figs 2-3 and Col. 7, Lines 64 - Col. 8, Line 51). Boury are silent with respect to first and second shape-memory frame members having a general tubular shape comprised of a superelastic material. Grabover et al. teach of an analogous apparatus provided with a handle and a flexible shaft connected to the handle. The flexible shaft has a passive deflection section and an active deflection section operated by a control wire. The passive deflection section has a sheath holding a portion of the control wire therein. The sheath is made from a superelastic alloy material and is resiliently

deflectable to bend with the passive deflection section without permanent deformation or substantial fatigue over a working life of the endoscope. The sheath has continuous column strength to support axial loads without cross-sectional and longitudinal deformation or loss of flexibility (see Figs. 2-3 and Col. 4, Lines 7-67). It would have been obvious to one skilled in the art at the time the invention was made to provide first and second shape-memory frame members having a general tubular shape comprised of a superelastic material in the apparatus of Boury to enhance the accuracy and total deflection of the active deflection section as taught by Grabover et al.

Response to Arguments

Applicant's arguments filed May 19, 2008 have been fully considered but they are not persuasive.

Applicant states that Boury fails to disclose first and second deflection sections limited to first and second planes, respectively. Examiner disagrees. Boury clearly discloses a first active deflection section 36a including a plurality of rings pivotably connected to each other and a second active 36b deflection section including a plurality of rings pivotably connected to each other, wherein the first active deflection section is limited to deflection in a first plane and the second active deflection section is limited to deflection in a second different plane, and wherein the first plane is angled to the second plane (see Figs 1-2 and Col. 7, Lines 64 - Col. 8, Line 51). Particularly, the formable length 30 in FIG. 1B extends along four different arcs of curvature. The first arc 36A extends from the proximal end of the manipulable length 30 to the first node 32A. The second arc 36B extends from the first node 32A to the second node 32B.

The third arc 36C extends from the second node 32B to the third node 32C. The fourth arc 36D extends from the third node 32C to the fourth node 32D. In the embodiment illustrated in FIGS. 1A and 1B, each of the four control wires is attached to a different node. In particular, control wire 34A is attached to node 32A; control wire 34B is attached to node 32B; control wire 34C is attached to node 32C; and control wire 34D is attached to node 32D. As these nodes are spaced from one another along the length of the catheter, the control wires will extend a different length along the length of the catheter before reaching the associated node. As the axis of the links are open, the control wires will be attached to the associated link 40" at a location spaced away from the link's axis. Pulling proximally on the wire, therefore, will exert an uneven force on the link, tending to pull just one side of the link proximally. The ability to curve the catheter in multiple planes is illustrated in FIGS. 2-4. FIG. 2 is a perspective view of a catheter having two distinct arcs 36A and 36B, each lying in a different plane. Alternatively, Boursy disclose that FIGS. 2-4 illustrate a catheter which is bent through just two arcs 36A and 36B. It should be understood, though, that the catheter can include many arcs. For instance, the control wires 34A-34D in FIG. 1B all lie in the plane of that figure, with two lying on one side of the catheter and two lying on the other side. (As noted above, only control wires 34A and 34B are shown along their full lengths; if shown, wire 34C would lie immediately adjacent wire 34A and wire 34D would lie immediately adjacent wire 34B.) If the control wires were spaced differently about the wall of the catheter, the catheter could be made to curve in as many as four different planes rather than in the single plane shown in FIG. 1B. Thus, as broadly as

claimed, Boury meet the limitations of the recited claims, as the individual pull wires are responsible for the deflection of one particular arc as they are connected to different nodes along the length of the catheter, and thus the first and second deflection sections limited to first and second planes.

In response to applicant's argument that the catheter is not adapted to be inserted through an incision in a renal pelvis of a patient, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Boury clearly disclose the use of renal catheters (see Col. 4, Lines 17-18). Furthermore, the words "adapted to" in the claims may be properly interpreted as "capable of," and "capable of" does not require that reference actually teach the intended use of the element, but merely that the reference does not make it so it is incapable of performing the intended use.

Applicant states that Boury fails to disclose means for viewing by an optical lens at the front of the shaft. Examiner disagrees. Firstly, Boury teach that it is well known in the art that Catheters (including both standard catheters and so-called vascular sheaths) are used in a wide variety of medical procedures. For example, some catheters are used to reach selected sites within the human vasculature so that a drug

can be delivered to a specific site. Alternatively, a second medical device, such as a stent or septal defect occlusion device, may be delivered to the desired location through the catheter. Other catheters include the capability to perform additional functions. For example, balloon catheters can be inflated to perform angioplasty or temporarily or permanently occlude a vessel. Other catheters include optical systems to permit a physician to visualize a remote site within the body, such as in endoscopy (see Col. 1, Lines 9-22). Secondly, Boury incorporates by reference, U.S. Patent No. 5,325,845 to Adair (see Col. 7, Line 30). Adair clearly discloses a steerable sheath for use with one of several selected removable optical catheters to be positioned within a body cavity of a patient for observation and/or treatment thereof (see Figs. 11-16 and Col. 6, Lines 10-45). Particularly, the catheter, as best seen in FIGS. 7, 9 and 10, can be provided with several passageways for different purposes. A fiber optic bundle 76 can include one or more optic fibers for transmitting light from the console to the distal end of the catheter to illuminate the site under investigation. In addition, bundle 76 will contain coherent fibers to project an image to the video screen associated Alternative catheter configurations which can be used within sheath 10 are shown in FIGS. 11-16. In this regard, FIGS. 11 and 12 show an optical catheter 18' which has a small fiber bundle 82 for transmitting light from a light source 84 to the site under investigation. The image is reflected back through optical bundle 86 to a video camera or image processing device 88. This device is connected by a cable 90 to a video monitor 92 which displays an image from the viewing site. Thus, as broadly as claimed, Boury meets the limitations of the recited claims as the disclosure of U.S. Patent No. 5,325,845 to Adair is fully

incorporated by reference and teaches of optical catheters for observing a bodily cavity, which Boury teaches is well known in the art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MATTHEW J. KASZTEJNA** whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. K./
Examiner, Art Unit 3739

/Linda C Dvorak/
Supervisory Patent Examiner, Art
Unit 3739

12/8/8